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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/523,218 | 10/19/2005 | Stevan Nielsen | 17601.25a.1 | 8376 |
| 57360 | 7590 | 03/29/2010 | EXAMINER | |
| WORKMAN NYDEGGER 1000 EAGLE GATE TOWER, 60 EAST SOUTH TEMPLE SALT LAKE CITY, UT 84111 | | | OU, JING RUI | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3773 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 03/29/2010 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | | |
|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 10/523,218 | | NIELSEN ET AL. | |
| | Examiner | | Art Unit | |
| | JING OU | | 3773 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-46 is/are pending in the application.
- 4a) Of the above claim(s) 41-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/04/2007 and 02/08/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is responsive to the non-provisional application filed on 01/31/2005 and the Election/Restriction response filed on 01/15/2010. Claims 24-46 are pending. Claim 24 is independent.

Election/Restrictions

2. Applicant's election without traverse of Species A (Figures 1-7B) in the reply filed on 01/15/2010 is acknowledged. Claims 41-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claim Objections

3. Claims 41-46 are objected to because of the following informalities: Claims 41-46 cannot be depending on the cancelled claims. Appropriate correction is required.

4. Claims 29-34 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 29-32 fails to further limit the subject matter of a previous claim because the closure agent is not positively recited in claim 24.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 24 and 27-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Hershberg (US Pat. No.: 3,572,336).

In regard to Claim 24 and 27-35, Hershberg discloses an apparatus comprising: a housing (10); a plurality of needles (24) coupled to the housing; a stop (bottom/base of the case 10) configured to limit translation of the plurality of needles into the tissue; an actuator (21); wherein each one of the plurality of needles comprises a distal tip, a distal aperture, and a lumen (Fig. 2).

7. Claims 24-26, 28-35, and 38-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Silverman et al (US Pat. No.: 6,251,063).

In regard to Claims 24-26, 28-35, and 38-40, Silverman et al discloses an apparatus comprising: a housing (21); a plurality of needles (Fig. 14) coupled to the housing; an expandable member (211) disposed from a distal end of a shaft (217) coupled to the housing; an actuator (22) coupled to the plurality of needles; wherein the closure agent is coated onto the plurality of needles (when the material is injected from the needle, some of the material is coated onto the needles, Fig. 17); wherein each one of the plurality of needles comprises a distal tip, a distal aperture, and a lumen (Fig. 14); a manifold (98) having an inlet port (Fig. 1).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hershberg (US Pat. No.: 5,372,336) as applied to claims 24 and 33 above, and further in view of Slater (US Pub. No.: 2002/0143291).

In regard to Claims 36 and 37, Hershberg discloses all the limitations of the claims but fails to disclose a radiopaque marker disposed adjacent to the distal tip of each one of the plurality of needles and on the distal end of the shaft. However, Slater teaches a radiopaque marker (58) disposed adjacent to the distal tip of a surgical

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insertion tool (26). At the time of the invention, it would have been obvious to modify the apparatus of Hershberg to include a radiopaque marker disposed adjacent to the distal tip of a surgical insertion tool as taught by Slater. Applicants should note that it was well-known to include a radiopaque marker/band adjacent to the distal tip of a surgical insertion tool to allow a surgeon to monitor the location of the insertion tool in the body.

12. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Silverman et al (US Pat. No.: 6,251,063) as applied to claims 24 above, and further in view of Epstein et al (US Pat. No.: 6,835,193)

In regard to Claim 27, Silverman et al discloses all the limitations of the claim but fails to disclose a stop to limit translation of the plurality of needles into the tissue. However, Epstein et al teaches an apparatus comprising a stop (15 and 14) to limit translation of a needle into body tissue. At the time of the invention, it would have been obvious to modify the apparatus of Silverman et al to include a stop as taught by Epstein et al for allowing the control of the depth injection of the needle into the body tissue (Epstein et al, see Abstract).

13. Claims 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverman et al (US Pat. No.: 6,251,063) as applied to claims 24 and 33 above, and further in view of Slater (US Pub. No.: 2002/0143291).

In regard to Claims 36 and 37, Silverman et al discloses all the limitations of the claims but fails to disclose a radiopaque marker disposed adjacent to the distal tip of each one of the plurality of needles and on the distal end of the shaft. However, Slater

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teaches a radiopaque marker (58) disposed adjacent to the distal tip of a surgical insertion tool (26). At the time of the invention, it would have been obvious to modify the apparatus of Silverman et al to include a radiopaque marker disposed adjacent to the distal tip of a surgical insertion tool as taught by Slater. Applicants should note that it was well-known to include a radiopaque marker/band adjacent to the distal tip of a surgical insertion tool to allow a surgeon to monitor the location of the insertion tool in the body.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

| | |
|-------------------|---------------------------------|
| US 20030028172 A1 | Epstein, Stephen et al. |
| US 20020082546 A1 | Crank, Justin et al. |
| US 7179266 B2 | Kontos; Stavros |
| US 5728114 A | Evans; Douglas et al. |
| US 6120786 A | Cherif Cheikh; Roland |
| US 20020123740 A1 | Flaherty, J. Christopher et al. |
| US 5049141 A | Olive; Peter |
| US 4863437 A | Clarke; Ellis W. |
| US 6663647 B2 | Reiley; Mark A. et al. |
| US 5275616 A | Fowler; Bradford C. |
| US 5830125 A | Scribner; Robert M. et al. |
| US 20020045928 A1 | Boekstegers, Peter |

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US 3625793 A Sheridan; David S. et al.

US 6302870 B1 Jacobsen; Stephen C. et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING OU whose telephone number is (571)270-5036.

The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Uyen (Jackie) T Ho can be reached on (571)272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. O./

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/Melanie Tyson/
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March 25, 2010